Statement-II

Details of samples of milk and milk products examined and found adulterated in Haryana

Sl. No.	Name of Food Articles	Haryana (05.08.11 to 31.12.12)	
		No. of samples Examined	Found Adulterated
1.	Milk and Milk Products	123	27

Illegal clinical drug trials

871. DR. PRADEEP KUMAR BALMUCHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the details of number of cases of illegal clinical trials that have taken place during the last two years;

(b) whether Government has initiated any steps to curtail such illegal clinical activities;

(c) if so, the details thereof; and

(d) the corrective measures being taken by Government to stop such tests?

THE MINISTER OF HEALTH AND FAMILY WELFARE (SHRI GHULAM NABI AZAD): (a) Six cases of alleged irregularities in conduct of clinical trial have been reported in the country during last two years.

(b) to (d) Following steps have been taken to strengthen the approval procedures and monitoring mechanism for clinical trials of drugs in the country to ensure that safety, rights and well-being of clinical trial participants are protected:

1. 12 New Drug Advisory Committees (NDAC) consisting of leading experts mostly from the Government medical colleges and institutes from all over the country have been constituted to adivse the Central Drugs Standard Control Organisation (CDSCO) in matters related to approval of clinical trials and new drugs.

2. Applications of Investigational New Drugs (IND) i.e, New Drug Substances which have never been used on human beings are evaluated by an IND Committee, chaired by the Director General, Indian Council of Medical Research (ICMR).

3. Registration of clinical trial in ICMR's registry at www.ctri.in has been made mandatory.

4. Guidelines for conducting inspection of clinical trial sites and sponsor/ Clinical Research Organizations (CROs) have been prepared.

5. To further strengthen the regulatory provisions and the monitoring mechanism of clinical trials in the country, the Drugs and Cosmetics Rules, 1945 have been amended as follows:

   A. Amendment vide Gazette Notification G.S.R. 53 (E) dated 30-01-2013 specifying procedures to analyse the reports of Serious Adverse Events occurring during clinical trials and procedures for payment of compensation in case of trial related injury or death as per prescribed timelines.

   B. Amendment vide Gazette Notification G.S.R. 63(E) dated 01-02-2013 specifying various conditions for conduct of clinical trials, authority for conducting clinical trial inspections and actions in case of non-compliance.

   C. Amendment vide Gazette Notification G.S.R No. 72(E) Dated 08.02.13 providing for the requirements and guidelines for registration of Ethics Committee.

Establishment of BSL IV laboratory

872. SHRI NAND KUMAR SAI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(d) whether ICMR has established the first Bio-Safety Level (BSL) IV Laboratory with the support from Department of Science and Technology;

(b) if so, the details thereof;

(c) the details of the salient features of the said laboratory;

(d) the manner in which Indian Medical system will be benefited by the BSL laboratory; and

(e) the details of the funds allocated and expenditure incurred in setting up of the said laboratory?